REMARKS

Claims 18-31 were pending in this application. With this Amendment, Applicants have cancelled Claims 18-31, and have added new claims 32-39. Thus, claims 32-39 are now at issue.

Translations

In the Office Action, the Examiner requested that Applicants submit English translations of Chinese patent nos. ZL94102798 and ZL94102799. Applicants attach these translations to the present Response. In addition, Applicants attach English translations of the priority document of PCT/CN04/00138 (CN03137133.7 and CN03141352.5).

Rejections Under 35 U.S.C. 112

Claims 18-31 were rejected under the second paragraph of 35 U.S.C. §112, on the grounds that they failed to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The newly submitted claims 32-39 are directed to a method of preparing a cardio myopeptidin from hearts of healthy non-human mammal, instead of a cardio myopeptidin. Thus, Applicants believe that they have overcome this rejection.

Claims 18-31 were rejected under the first paragraph of 35 U.S.C. §112, as failing to comply with the written description requirement. The newly submitted claims 32-39 have been modified in relation to the prior claims to remove the matter that was noted.

In view of the foregoing, reconsideration and withdrawal of these rejections under 35 U.S.C. §112 is respectfully requested.

Rejections Under 35 U.S.C. 102 (a or b) and 35 U.S.C. 103(a)

Claims 18-31 were rejected under 35 U.S.C. §102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over ZL94102798, ZL94102799. These Chinese patents ZL94102798.8 (D1) and ZL94102799 (D2), the English translations of which are

attached hereto, were published on September 20, 1995. Applicants respectfully acknowledge that these references qualify as prior art in relation to the present application.

D1 discloses a method for the preparation of cardio myopeptidin (GMGSP) which includes the steps of: selecting the hearts of healthy non-human infant mammals and crushing the same with mechanical means; deep freezing the crushed hearts of healthy non-human infant mammals at -20 degrees C and heating to 60-100 degrees C for 15 minutes after being melted; cooling to room temperature; deep re-freezing at -20 degrees C and re-melting; centrifuging at 3000prm for 30 minutes to obtain the supernatant; and processing the supernatant by passing through negative pressure interception column, sterilizing, filling, lyophilizing and packing to obtain GMGSP, which the interception molecular weight is **less than 20000 Da**.

It is noted that the difference between the subject matter in claim 32 of the present invention and D1 are at least as follows (which are also shown in Table 1 below):

(1) in step (e) of new claim 32, the coarse filtrate is obtained by **filtering the homogenate using a plate-and-frame filter**, not by **centrifuging the solution** to obtain a supernatant as disclosed in D1.

(2) in step (f) of new claim 32, a fine filtrate having a molecular weight of less than 12000 Da is obtained by ultra-filtering the coarse filtrate with a hollow-fiber column, whereas a hollow fiber ultrafiltration column comprising one or more columns connecting in series, the molecular weight is less than 20000 Da after processing the supernatant by passing through a hollow fiber ultrafiltration column as disclosed in D1;

(3) D1 does not disclose step (g) of new claim 32, specifically "**ultra-filtering the fine filtrate using an ultrafiltration membrane to obtain the cardio myopeptidin solution with a molecular weight in the range from 2000 to 8000 Da**";

(4) D1 does not disclose step (h) of claim 32, specifically "**concentrating the cardio myopeptidin solution by reverse osmosis to obtain a concentrated cardio myopeptidin solution**";

(5) the product resulting from the method is also different in that D1 does not disclose **a cardio myopeptidin (GMGSP) comprising: 75% to 90% of peptide; 6% to 15% of free amino acid; less than 2% of ribonucleic acid; and less than 7.5% of deoxyribonucleic acid.**

Table 1: Comparison of Claim 32 With ZL94102798.8 (D1)

The present invention (US Application Serial No. 10/567.286)	ZL94102798.8 (D1)
1, A method of preparing a cardio myopeptidin from hearts of healthy non-human mammals by a process comprising the steps of:	myocardial cells (GMGSP) prepared from hearts of healthy non-human mammals
(a) cleaning and cutting the hearts of healthy non-human mammals;	the hearts of healthy non-human infant mammals(in claim1)
(b) homogenizing the hearts by adding sterile distilled water to the myocardium of the hearts of healthy non-human mammals which is cleaned and cut, thereby creating homogenate;	crushing with mechanical means (in claim1)
(c) freezing and thawing the homogenate for *at least 3 cycles;*	the freeze and melt method can be repeated one or more times.(in the specification),

(d) heating the homogenate to **65 to 95 degrees C**	**heating to 60-100 degrees C**,
(e) **filtering the homogenate using a plate-and-frame filter to obtain a coarse filtrate,** and removing a residue resulting from the filtering;	**centrifuging at 3000prm** for 30 minutes to obtain a supernatant,
(f) ultra-filtering the coarse filtrate with a hollow-fiber column to obtain a fine filtrate having a molecular weight of less than 12000 Da;	the supernatant is processed through a hollow fiber ultrafiltration column, and the interception molecular weight is less than 20000 Da.
(g) ultra-filtering the fine filtrate using an ultrafiltration membrane to obtain the cardio myopeptidin solution with a molecular weight in the range from 2000 to 8000 Da; and	
(h) concentrating the cardio myopeptidin solution by reverse osmosis to obtain a concentrated cardio myopeptidin solution;	
(i) testing the quality of concentrated cardio myopeptidin solution; and,	

(j) filtering aseptically, filling, and lyophilizing the concentrated cardio myopeptidin to obtain a polypeptide comprising: 75% to 90% of peptide; 6% to 15% of free amino acid; less than 2% of ribonucleic acid; and, less than 7.5% of deoxyribonucleic acid; wherein the cardio myopeptidin shows four to five principal peaks on an HPLC analysis spectrum, with a relative peak area of more than 85%.	sterilizing, filling, lyophilizing and packing

D2 disclosed a medicament comprising GMGSP which is isolated from the hearts of healthy infant mammals. The method for the preparation of GMGSP is not disclosed or taught in the specification of D2, although D2 may disclose the biochemical characteristics of GMGSP, such as stable pH, biological activity, stable lyophilizing, stable heating, MW and HPLC, as suggested in the Office Action.

However, the method preparing the cardio myopeptidin of the present invention is for an isolated composition which may not be analyzed by MS or H-NMR et al. to show the traditional physical and or chemical properties. In claim 32, the invention is directed to a method of preparing GMGSP, with specific limitations on the components and the molecular weight. It is noted that the molecular weight of the cardio myopeptidin in claim 32 of the present invention is in the range from 2000 to 8000 Da and the relative peak area is more than 85% on HPLC analysis spectrum, not 8500Da, 10800Da or 5000-12000Da and 60.4% (10.4%+6.4%+36.3%+7.3%) as disclosed in D2. A significantly different portion of the isolated

mixture from non-human infant mammals is chosen for the subject matter of claim 32 of the present invention.

At least dependent claims 33 and 35 further indicate that the method of the present invention is different from D2 as shown in Table 2, as set out below.

Table 2: Comparison of Claims 33-39 With ZL94102799.6 (D2)

The present invention (US Application Serials No. 10/567.286)	ZL94102799.6 (D2)
33. The method of claim 32 wherein a weight average of the molecular weight is in the range from 2000 to 5000 Da.	8500Da,10800Da, or 5000-12000Da
35. The method of claim 32 wherein an isoelectrofocusing electrophoresis of the cardio myopeptidin displays 2 to 6 stained bands; wherein the cardio myopeptidin has a stable maximum absorption peak at 190 to 210 nm wavelength within a UV spectrum, and wherein the cardio	the molecular weights of two bands displayed by SDS-PAGE analysis GMGSP has two characteristic absorption peaks at 195±2nm and 255±2nm wavelength in the UV spectrum

myopeptidin shows five peaks on an FPLC analysis spectrum, with a sum of relative area from 90% to 95%.	

Thus, the claimed subject matter in at least claim 32, 33, and 35 of the present invention is not anticipated by any one of D1 or D2. Since D1 and D2 do not disclose, nor otherwise suggest to one of ordinary skill in the art, the method for the preparation of cardio myopeptidin, nor the component or molecular weight of cardio myopeptidin, as set out in claim 32 of the present invention, claim 32 of the present invention is not obvious upon the combination of D1 and D2.

In view of the foregoing, reconsideration and withdrawal of the rejections based upon D1 and/or D2 is respectfully requested.

CONCLUSION

Applicants request entry of the present amendments and examination of the pending claims in view thereof. Commissioner is authorized to charge any fee deficiency, or credit any overpayments, to Deposit Account No. 502261. The Examiner is invited to contact the undersigned if the Examiner believes a telephone conference would expedite allowance of the present claims and application.

Respectfully submitted,

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